REMARKS

Claims 1 and 6 have been amended to recite that the albumin preparation claimed therein is in a form suitable for administration to a patient for treatment of liver diseases. This limitation is supported throughout the specification by the disclosure of the preparation as being used for the treatment of liver diseases.

Claim 7 has been amended to recite the claimed use using proper method format.

New claims 8 and 9 have been added to the application and recite that the albumin preparation of claims 1 and 6, respectively, is in the form of a sterilized aqueous solution. This limitation is supported by the description of the albumin preparation of the present invention on page 8, lines 12-15.

Reconsideration and removal of the objection to the use of "trademarks" in the specification and of the rejections of the claims is respectfully requested.

First, regarding the objection to the use in the specification of the terms "AMINOLEBAN" and "MORIHEPAMIN", the objection is not proper. Table 1 on page 6 of the specification sets forth a

description of a preferred amino acid composition including branched amino acids useful in the present invention. The specification describes that solutions comprising the amino acid composition as described in Table 1 are available as conventional drug preparations under the names "AMINOLEBAN" and "MORIHEPAMIN", neither of which appears to be a registered trademark in the United States. The producers of the preparations are also described.

The primary issue regarding the use of trademarks in the specification of a United States patent application is sufficiency of disclosure. If a specification merely describes a component of a composition claimed in the application according to a trademark, more may be required. In the present application, however, a preferred amino acid composition including branched amino acids useful in the present invention is specifically described. The specification of the present application does not use trademarks to comply with the requirements of 35 U.S.C. § 112, first paragraph. Removal of the objection is in order.

Claims 1-3 and 7 are rejected under 35 U.S.C. §102(b) as being anticipated by EP 0 683 233 ("EP '233"). EP '233 discloses a process for producing human serum albumin in a medium that contains

an amino acid. The position of the Office is believed to be that claims 1-3 of the application read on a culture medium as described in the application in which albumin has been cultured (prior to isolation and purification of the albumin). Claim 7 has been rejected as reciting an intended use that does not impart patentability to the composition.

Initially, applicants note that EP '233 does not disclose an albumin preparation containing 0.01 to 1.0 w/v % of albumin as recited in claim 2. Thus, the rejection, at least as applied to claim 2, is clearly incorrect.

Claims 1 and 6 have been amended, as noted above, to recite that the albumin preparation of the present invention is in a form suitable for administration to a patient for treatment of liver diseases. Claim 7 has been amended to properly define the use of the albumin preparation of the present invention for the treatment of liver diseases. A culture medium, as disclosed in EP '233, is not a preparation in a form suitable for administration to a patient and EP '233 does not disclose or suggest the use of the culture medium disclosed therein for the treatment of liver diseases. New claims 8 and 9 further define the form of the

preparation as a sterilized aqueous solution. EP '233 does not disclose an albumin preparation in the form of a sterilized aqueous solution.

EP '233 is insufficient to support the 35 U.S.C. § 102 rejection of the claims, particularly as amended, and removal of this rejection is in order.

Claims 1-7 are rejected under 35 U.S.C. §103(a) as being unpatentable over EP '233 taken with WO 88/01861 ("WO '861") or Ohashi et al. (U.S. Patent No. 4,499,076) ("Ohashi"). The Office appears to be suggesting that the yield percentages in Tables 2-4 of EP '233 are related to the content of branched amino acids in the culture mediums disclosed in EP '233. The yield percentages, however, are the yields of albumin obtained under varying culture conditions, e.g., concentration of His (Test Example 2), and suggest nothing concerning a concentration of branched amino acids in the culture mediums.

The secondary references are alleged to somehow provide a motive for adjusting the content of branched amino acids in the culture medium disclosed in EP '233. The secondary references, however, are unrelated to conditions for culturing human serum

albumin and do not provide a motive for using a plurality of amino acids containing a specified amount of branched amino acids in the culture medium disclosed in EP '233 or for otherwise modifying the culture medium of EP '233. For these reasons alone, the 35 U.S.C. § 103(a) rejection is improper. Moreover, even if the culture medium disclosed in EP '233 was modified to include a plurality of amino acids containing a specified amount of branched amino acids, an albumin preparation in a form suitable for administration to a patient would not be obtained.

Removal of the 35 U.S.C. § 103(a) rejection is also in order.

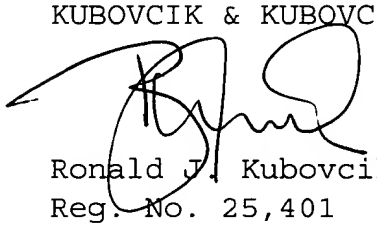
The foregoing is believed to be a complete and proper response to the Office Action dated September 24, 2003, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK



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